

# **CON Regulation of Organ Transplant Services in Maryland: a White Paper by the Maryland Health Care Commission's Center for Health Care Facilities Planning and Development**

## **Introduction**

COMAR 10.24.15, the State Health Plan for Facilities and Services (SHP): Specialized Health Care Services – Organ Transplant Services, is used by the Maryland Health Care Commission (MHCC) for Certificate of Need (CON) oversight and regulation of solid organ programs and hematopoietic stem cell (bone marrow) and other transplantable cell programs at Maryland hospitals. The CON program ensures oversight of existing facilities and appropriate distribution of new or expanded facilities, as well as oversight of consolidations and mergers of services and programs within hospital systems. The latest revision of COMAR 10.24.15 became effective on April 15, 2002. COMAR 10.24.15 specifies requirements to obtain a CON for the establishment of new solid organ and transplantable cell programs, as well as continuing performance standards that must be met by existing transplant programs.

This paper has been prepared by MHCC staff to precede a review and update of the current information, principles, policies, standards, methodologies, and definitions in COMAR 10.24.15. This paper outlines general issues related to organ transplantation in order to introduce a baseline of knowledge regarding this specialized service. It also reflects on changes that might be appropriate to incorporate into COMAR 10.24.15 to improve MHCC's regulatory oversight. Additionally, the Johns Hopkins Hospital has expressed interest in developing a kidney transplant program in Montgomery County to serve patients within a designated region that includes Charles, Montgomery, and Prince George's Counties, Washington, D.C., and northern Virginia.

MHCC will convene an advisory group to address issues discussed in this paper, along with other concerns that may need to be taken up during the process. MHCC staff looks forward to further exploring the considerations outlined in this paper with the advisory group members and offering final recommendations on updates to COMAR 10.24.15 after a comprehensive collaborative planning process.

## *Organ transplantation history and regulation*

Organ transplantation is the process of surgically transferring a donated organ into a patient with end stage organ failure. Deceased donors provide kidneys, pancreas, liver, lungs, heart, intestines, and bone marrow. Living donors can provide a kidney, a portion of the liver, lung or

intestine, and bone marrow.<sup>1</sup> Organ transplantation is often the only treatment for end stage organ failure of the liver and heart. Kidney transplantation, the most frequent transplantation procedure globally, is also the most cost effective treatment for end stage renal disease, a condition that can be managed with peritoneal dialysis or hemodialysis.<sup>2</sup> Vascular composite allografts (VCAs), which are transfers of skin, muscle, bone, and nerve which were previously under the regulatory jurisdiction of the Food and Drug Administration, were also added to the Department of Health and Human Services' (HHS') definition of transplantable organs in 2013.<sup>3</sup>

The Uniform Anatomical Gift Act of 1968 provides the legal foundation in the U.S. upon which human organs and tissues can be donated for transplantation as a gift to an appropriate medical facility.<sup>4</sup> Since 1968, additional laws have defined death and legal consent to donate, extended Medicare coverage for end stage organ failure, provided funding mechanisms to support the organ transplantation process, and criminalized the exchange of organs for value.<sup>5</sup> The National Organ Transplant Act (NOTA) of 1984 called for the creation of a national Organ Procurement and Transplantation Network (OPTN) in response to the growing need for donor organs and for a more centralized and national organ donation registry. Before this law was passed, hospitals and regional hospital collaborations relied on a supply of donor organs within their own networks for their own patients in need.

HHS awarded the national OPTN contract to the United Network for Organ Sharing (UNOS) in 1986. UNOS is the only organization to operate the OPTN since its inception. In 2000 HHS established a regulatory framework for the structure and operations of the OPTN. UNOS develops, monitors, and enforces the rules governing allocation, procurement, and transplantation of all organs (not including bone marrow transplants), as approved HHS.<sup>6</sup>

UNOS divides the U.S. into 11 regions. This regional system provides a mechanism for communication between UNOS and the transplant community and helps to ensure geographic diversity among collaborative transplant professionals. Regional staff also coordinate regional meetings and education events.<sup>7</sup> Maryland falls within Region 2, which also includes Delaware, the District of Columbia (D.C.), New Jersey, Pennsylvania, West Virginia, and Northern Virginia.

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<sup>1</sup> U.S. Department of Health and Human Services (website: <http://organdonor.gov>)

<sup>2</sup> World Health Organization (website: <http://www.who.int/transplantation/organ/en/>)

<sup>3</sup> U.S. Government Printing Office's Federal Register published July 3, 2013 (website: <http://www.gpo.gov/fdsys/pkg/FR-2013-07-03/html/2013-15731.htm>)

<sup>4</sup> U.S. Department of Health and Human Services (website: <http://organdonor.gov/legislation/legislationhistory.html>)

<sup>5</sup> U.S. Department of Health and Human Services (website: <http://organdonor.gov/legislation/legislationhistory.html>)

<sup>6</sup> United Network for Organ Sharing (website: [http://www.unos.org/donation/index.php?topic=policy\\_development](http://www.unos.org/donation/index.php?topic=policy_development))

<sup>7</sup> U.S. Department of Health and Human Services Health Resources and Services Administration (website: <http://optn.transplant.hrsa.gov/members/regions.asp>)

Within regions, Organ Procurement Organizations (OPOs) are designated by HHS' Centers for Medicare and Medicaid Services (CMS) to facilitate organ procurement and transplantation at the local level. OPOs are private non-profit organizations that receive government funding to promote donor registration, verify consent for organ donation, evaluate donors, help match donors to recipients, and coordinate recovery and transportation of organs to transplant centers. CMS certifies and provides oversight of OPOs, and all OPOs are members of the OPTN.

OPOs work closely with transplant hospitals to optimize the number of organ transplantations. Every transplant hospital is also a member of the OPTN. All organ transplant programs are hospital-based and specific to the type of organ. Two or more transplant programs for specific organs are often located at the same hospital under one transplant center.<sup>8</sup>

In 2007, CMS revised its Conditions of Participation for organ transplant programs.<sup>9</sup> These revised conditions include staffing requirements, clinical experience requirements, and outcome standards. In general, CMS requires that programs perform at least ten transplants over a 12-month period for re-approval for kidney, liver, heart, lung, and intestine transplant programs. Outcome standards are based on a comparison of the number of patient deaths and graft failures within one year following a transplant considering the center's expected number of risk-adjusted post-transplant deaths and failures, when volumes allow a valid comparison. The conditions also include data submission requirements to OPTN. For the VCAs added to the definition of organ transplantation effective in 2014, UNOS and CMS are expected to develop standards and policies.<sup>10</sup> CMS Conditions do not apply to programs performing bone marrow and stem cell transplantation.

### *Organ Procurement Process*

Potential organ transplant recipients are evaluated by transplant physicians to determine if and when they should be placed on the UNOS waiting list. Rules that dictate the waiting list vary by organ. Matching criteria include a patient's medical urgency; blood type, tissue and size match with the donor; time on the waiting list; and geographic proximity to the donor. Under certain circumstances, special allowances may be made for children. Factors such as a patient's race or ethnic background, income, and social status do not factor into a determination of organ allocation.<sup>11</sup> Donated organs must be preserved in solutions at low temperatures and transported to donors in a timely manner, which restricts the acceptable distance between donor and recipient. UNOS' computer system is programmed to determine and prioritize potential matches.

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<sup>8</sup> U.S. Department of Health and Human Services Health Resources and Services Administration (website: [http://opotxfind.hrsa.gov/Search\\_OPO\\_OTC.aspx](http://opotxfind.hrsa.gov/Search_OPO_OTC.aspx))

<sup>9</sup> U.S. Government Printing Office's Federal Register published March 30, 2013 (website: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/Transplantfinal.pdf>)

<sup>10</sup> U.S. Government Printing Office's Federal Register published July 3, 2013 (website: <http://www.gpo.gov/fdsys/pkg/FR-2013-07-03/html/2013-15731.htm>)

<sup>11</sup> The Living Legacy Foundation (website: <http://www.thellf.org/recipients/transplant-process.html>)

After a list of patients who match the donor is generated, the organ is offered to the first patient on the match list. Organs not matched within the OPO are shared with patients in the region, and organs not matched within the region are shared with other regions of the country. At the hospital, the donor is maintained on artificial support and the condition of each organ is carefully monitored by the hospital medical staff and the OPO procurement coordinator. The OPO representative makes arrangements for transplant surgical teams. The method of transportation varies based on the distance organs must travel, most often involving either commercial or contracted airplanes, helicopters, and ambulances.<sup>12</sup>

### *Bone Marrow and Other Hematopoietic Stem Cell Transplantation*

Bone marrow transplantation is a procedure to replace damaged or destroyed bone marrow with healthy bone marrow stem cells. This includes two kinds of bone marrow transplants: (1) autologous cells removed from the recipient's own body and stored to treat the patient after chemotherapy or radiation treatment and (2) allogeneic cells removed from another person, including from umbilical cord blood, which closely match the genes of the donor.<sup>13</sup> A bone marrow or cord blood transplant replaces a patient's diseased blood-forming cells with healthy ones in people who have a blood cancer, such as leukemia or lymphoma, or an inherited metabolic or immune system disorder.<sup>14</sup> MHCC also regulates other cell transplants that are harvested from a donor and transplanted to a recipient, including islet cells (found in the pancreas) and hepatocyte cells (liver cells).

The Stem Cell Therapeutic and Research Act of 2005 and the Stem Cell Therapeutic and Research Reauthorization Act of 2010 establish HHS's authority to regulate bone marrow and cell transplants. The Stem Cell Acts of 2005 and 2010 require the Secretary of HHS to contract with qualified cord blood banks and establish the four following components of cell transplantation process. The Office of Patient Advocacy and Single Point of Access provide support to patients and families and a centralized electronic registry for doctors, transplant center coordinators, and patients and families to search for marrow donors and donated cord blood units. The Bone Marrow Coordinating Center matches donors with patients, recruits and assists donors, and works with its network of organizations throughout the transplant process. The Cord Blood Coordinating Center recruits expectant parents for umbilical cord donation and increases access to transplant by matching and facilitating distribution of donated cord blood units searched through the registry. Lastly, the Stem Cell Therapeutic Outcomes Database is used to collect data about bone marrow and cord blood transplantation for research.<sup>15</sup>

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<sup>12</sup> U.S. Department of Health and Human Services (website: <http://organdonor.gov/about/organdonationprocess.html>)

<sup>13</sup> National Institutes of Health (website: <http://www.nlm.nih.gov/medlineplus/ency/article/003009.htm>)

<sup>14</sup> U.S. Department of Health and Human Services Health Resources and Services Administration (website: [http://bloodcell.transplant.hrsa.gov/about/legislation\\_and\\_contracts/](http://bloodcell.transplant.hrsa.gov/about/legislation_and_contracts/))

<sup>15</sup> Ibid.

### *Organ Procurement Organizations and Transplantation Centers in Maryland*

Two OPOs are certified by CMS to operate within Maryland. CMS designates Donation Service Areas (DSAs) for all OPOs, with only one OPO assigned to each jurisdiction. The Living Legacy Foundation (LLF), formerly the Transplant Resource Center of Maryland, is based in Baltimore and serves all Maryland jurisdictions with the exception of Charles, Montgomery, and Prince George's Counties. LLF was originally established in 1979 as the Greater Baltimore Organ Procurement and Perfusion Center. The Washington Regional Transplant Community (WRTC), formerly Washington Regional Transplant Consortium, serves Charles, Montgomery, and Prince George's Counties, D.C., and fourteen northern Virginia jurisdictions. The WRTC, based in Annandale, Virginia, was formed in 1986 and certified in 1988.

Table 1 provides details regarding these OPOs, hospitals within the OPOs' jurisdictions, and the population of the OPOs' jurisdictions. The WRTC's DSA includes counties that are not listed in the current State Health Plan for organ transplant services. Clarke, King George and Spotsylvania Counties in Virginia are within WRTC's DSA. D.C. also recently awarded a CON in February 2014 to George Washington University Hospital to establish kidney and pancreas transplant services. This new program will be in the WRTC region, in which Johns Hopkins is interested in developing a new kidney transplantation program.

Additionally, two hospitals in Maryland, one hospital in Washington, D.C., and one hospital in northern Virginia are accredited by the Foundation for Accreditation for Cellular Therapy (FACT) for bone marrow transplantation: The Johns Hopkins Hospital, University of Maryland Medical Center, Children's National Medical Center, and Inova Fairfax Hospital.

**Table 1: Details on Organ Procurement Organizations and Transplant Programs  
Serving the Population of Maryland**

<b>CMS-certified Organ Procurement Organization</b>	<b>The Living Legacy Foundation</b>	<b>Washington Regional Transplant Community</b>
<b>Jurisdictions Served</b>	Allegany, Anne Arundel, Baltimore, Calvert, Caroline, Carroll, Cecil, Dorchester, Frederick, Garrett, Harford, Howard, Kent, Queen Anne's, Somerset, St. Mary's, Talbot, Washington, Wicomico, and Worcester Counties and Baltimore City	MD Jurisdictions – Charles, Montgomery, and Prince George's Counties  VA Jurisdictions – Arlington, Clarke, Fairfax, Fauquier, Loudoun, King George, Prince William, Spotsylvania, and Stafford Counties and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park  Washington, D.C.
<b>Transplant Centers within OPO Jurisdictions</b>	The Johns Hopkins Hospital  University of Maryland Medical Center	Children's National Medical Center  George Washington University Hospital*  Inova Fairfax Hospital  MedStar Georgetown University Medical Center  MedStar Washington Hospital Center  Walter Reed National Military Medical Center
<b>Population of area Covered by OPO</b>	3.86 million	5.27 million
<b>Percentage of Maryland's Population Covered within OPO</b>	66%	34%
<b>Number of Donation Hospitals within region</b>	37	49

Sources: Living Legacy Foundation (website: <http://www.thellf.org/>), Washington Regional Transplant Community (website: <http://www.beadonor.org>), Department of Health and Human Services Centers for Medicare and Medicaid Services; Population data from the U.S. Bureau of the Census, University of Virginia Weldon Cooper Center, and Maryland Department of Planning

\*On April 11, 2014, the District of Columbia's State Health Planning and Development Agency awarded District Hospital Partners a Certificate of Need to establish kidney and pancreas transplant services at George Washington University. The certificate to establish these services is valid until April 11, 2015.

### **The State Health Plan and Transplantation Program Regulation in Maryland**

In Maryland, the establishment of organ transplantation programs is also regulated under the CON program, administered by MHCC. COMAR 10.24.15 of the SHP provides the criteria and standards for use in CON regulation of these services. MHCC regulates the supply and distribution of facilities that provide solid organ transplants (kidney, liver, pancreas, heart, and lung) and intestine or small bowel transplants, as well as hematopoietic stem cell transplants and

other transplantable cells in order to ensure that these facilities in Maryland meet minimum standards and meet the need for these services in Maryland. Under the SHP, a hospital must obtain a CON for each organ or tissue category of transplantation service that it proposes to provide. The ability to provide one type of transplant program does not enable a hospital to perform any other type of transplant because surgical specializations and post-surgical management needs are unique for each organ transplant type.

As defined by the SHP, transplantation falls under the category of tertiary care, a specialized service that requires a hospital setting with the most advanced array of supporting diagnostic and therapeutic services. Tertiary care is typically provided late in the disease process to patients who are severely ill or who are at the highest risk for poor outcomes. Their cost of care tends to be comparatively high. Delivery of these specialized services is planned and implemented at a regional or statewide level due to the advanced skills and equipment necessary to provide quality and cost-effective services to a limited number of patients. In the case of organ transplantation, overall utilization is also limited by organ availability.

In the current SHP, under COMAR 10.24.15.04B(3), it states that planning regions for organ transplantation will be consistent with CMS' OPO designations. This section also suggests that regional planning areas will change, as needed, to reflect any changes in OPO designations. As shown in Table 1, WRTC's jurisdictions include three additional Virginia counties that are not currently listed in COMAR 10.24.15.

In the current SHP, planning policies indicate that fewer organ transplant programs operating at higher volumes are preferable to more programs operating at threshold or minimum levels. Policy 4 sets minimum volume requirements for new programs to meet within 36 months of beginning operation and to maintain in each subsequent year of operation. Programs that fail to meet these volume requirements for any two consecutive years must close. MHCC relied on a Technical Advisory Committee on Organ Transplant Services to guide its decision on minimum volume requirements. These levels were set at 30 for kidney transplant programs, 12 for all other solid organ transplant programs (liver, pancreas, heart, lung, and heart-lung), and ten for autologous and allogeneic hematopoietic stem cell transplant programs for the last revision of COMAR 10.24.15. Requirements for intestine/small bowel transplant programs are determined by MHCC on a case by case basis; however, CMS incorporated a minimum volume requirement of ten intestinal transplants per year in 2000 for these programs.<sup>16</sup> Islet cells and hepatocytes are

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<sup>16</sup> U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (website:

also determined by MHCC on a case by case basis; there are no FDA guidelines for minimum volume requirements for these programs.

The most recent minimum volumes for organ transplantation programs set by CMS and UNOS are lower than those listed in COMAR 10.24.15. New heart, intestine, liver, and lung transplant centers are required to perform ten transplants over a 12 month period, while new kidney transplant centers are required to perform at least three transplants over a 12 month period. For re-approval, all transplant centers must perform an average of ten transplants per year over a three-year re-approval period. There is no volume requirement for heart-lung and pancreas centers, or centers that primarily perform pediatric transplants. HHS explained the need for different initial requirements for kidney transplant centers in the *Federal Register* on March 30, 2007. There are barriers to access to kidney transplantation services in some areas of the country where there are large dialysis populations but few kidney transplant centers. Medicare is the primary or secondary payer for 69 percent of kidney transplants performed in the U.S. and will not pay for beneficiaries to receive transplants at the facility until the center receives Medicare approval. Thus, a new kidney transplant center may have difficulty finding ten non-Medicare patients to transplant prior to approval, which may prevent kidney transplant centers from opening in areas where access to kidney transplant services is already limited.<sup>17</sup> At this time, while definitions, standards, and policies related to VCAs have been established by UNOS and initial national policies and standard will be in effect for 15 months<sup>18</sup>, CMS has not set minimum volume requirements for these programs. However, in order to be a VCA transplant program, UNOS requires that the hospital have current designated transplant program approval for at least one organ.<sup>19</sup> MHCC staff believes it is appropriate to expect final standards to guide future updates and decisions, as needed, for the regulation of this service.

COMAR 10.24.15 Policy 5 also reinforces the preference for higher volumes at existing programs, instead of opening a new organ transplant program. A new kidney transplant program will be approved only if existing programs have maintained a threshold volume of 50 transplants. The threshold volume for a new program is set at 20 transplants for liver, pancreas, heart, lung, and heart/lung transplant programs; ten for autologous stem cell transplant programs and 40 for allogeneic stem cell transplant programs. Thresholds for a new transplant program for intestine/small bowel, islet cells, and hepatocytes will be determined by MHCC on a case by case basis. If one program is operating below the threshold volume at the time of an application for a new program, MHCC will consider the new program only after analyzing need projections,

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<sup>17</sup> U.S. Government Printing Office's Federal Register published March 30, 2013 (website: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/Transplantfinal.pdf>)

<sup>18</sup> U.S. Government Printing Office's Federal Register published July 3, 2013 (website: <http://www.gpo.gov/fdsys/pkg/FR-2013-07-03/html/2013-15731.htm>) and UNOS (website: <http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=1653>)

<sup>19</sup> UNOS (website: [http://optn.transplant.hrsa.gov/committeereports/board\\_main\\_vascularizedcompositeallografttransplantation\\_6\\_16\\_2014\\_16\\_21.pdf](http://optn.transplant.hrsa.gov/committeereports/board_main_vascularizedcompositeallografttransplantation_6_16_2014_16_21.pdf))



trends in the supply of organs, the source of the applicant's new patients, and other relevant information about existing low volumes.

SHP policy requires each organ transplant program to be certified by UNOS within the first year of operation and each hematopoietic stem cell bone marrow transplant program to be accredited by the Foundation for the Accreditation of Cellular Therapy within the first two years of operation. The SHP also states that organ transplant centers should be accessible within a three hour one-way driving time to at least 95 percent of Maryland's population, a characteristic of all of the existing transplant centers in Maryland.

The SHP contains a methodology for forecasting the demand for organ transplantation within OPO regions. The forecast model accounts for migration patterns across OPO regional boundaries. The need for transplantation program capacity is based on the demand forecast and the supply of services. Solid organ transplantation need projections were updated effective March 21, 2014 and published in the *Maryland Register*. A copy is provided in Appendix I.

The latest need projections indicate that additional transplant program capacity is not needed in either of the OPO regions that include Maryland jurisdictions with respect to kidney, heart, lung, or pancreas transplantation. The forecast for the net need for liver transplant cases surpassed the threshold volume of 20 cases in both OPO regions and all programs operated above the threshold volume. Thus, under the current State Health Plan, this would allow for docketing and review of proposals for additional liver transplantation program capacity in both regions. While MHCC projects a net need for 27 additional kidney transplants in the Washington region and 11 additional transplants in the Maryland region, these net need levels do not exceed the current threshold volume of 50, which would trigger eligibility to apply for a new program. There is also a net need projected in the Maryland region for 11 lung transplants, which also does not meet the threshold volume requirement to trigger the need for a new program. Intestine transplants were only reported at one hospital, Georgetown University Medical Center, in the two OPO regions serving Maryland during the base years of 2010 through 2012 and no volume threshold has been established in the State Health Plan for this organ category.<sup>20</sup>

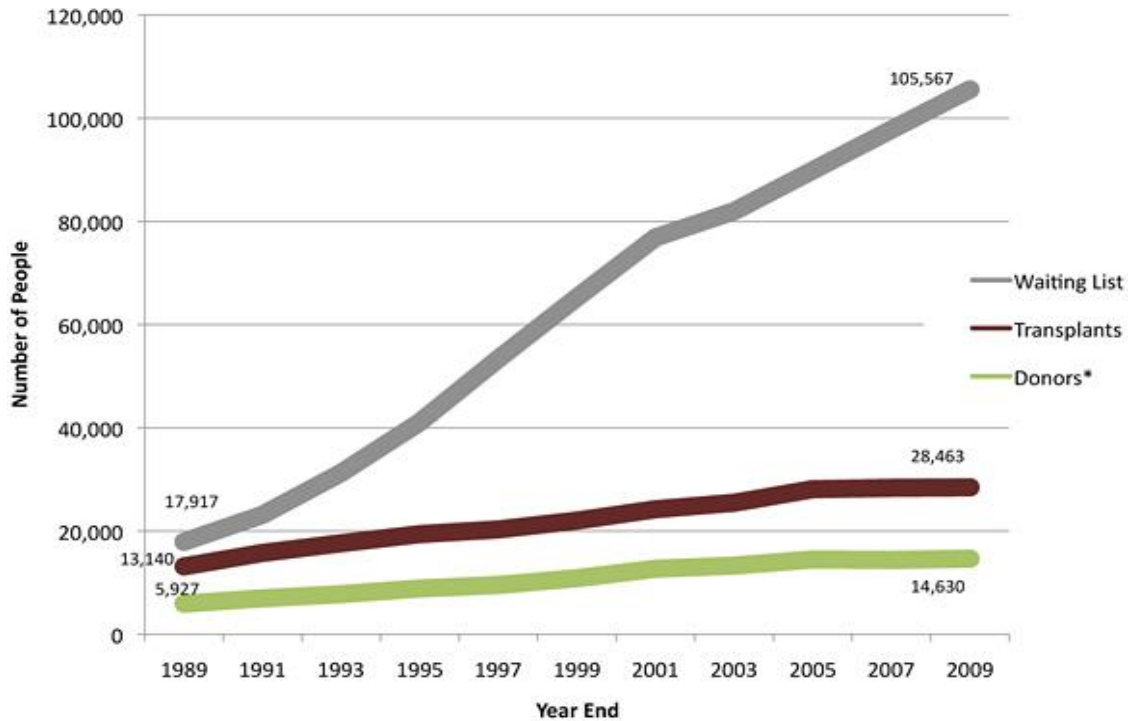
### **Recent Experience in Organ Transplantation in OPOs and Transplant Centers That Serve Maryland Residents**

An important consideration is that while demand increases for organs, the ability to provide this service to patients is still reliant upon the supply of donated organs. As shown in the graph below, the demand for organs across the U.S. has risen much more in the last 20 years than the number of donors and transplants.

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<sup>20</sup> CMS' annual clinical experience requirement for intestine transplant centers is 10 per year.

**Figure 1: Waiting List, Transplants, and Donors  
for All Organs in the U.S., CY 1989-2009**



Source: OPTN, graph found at <http://www.organdonor.gov/about/data.html>

\* Deceased and living donors

Table 2 reflects the latest organ transplant data available through UNOS for the regions currently published in COMAR 10.24.15. Using UNOS data and population estimates for this defined region, MHCC calculated and compared the rate of transplants per million for residents in each OPO region. Over the five-year period since 2009, kidney, liver, and lung transplantation procedures were consistently performed at a higher rate in the LLF OPO than the WRTC OPO. As seen in Table 2 below, for the period 2009 to 2013, the LLF performed kidney transplants at rate that was between 13% and 39% higher as compared to the WRTC OPO. Similarly, the rate of liver transplants was between 11 and 62% higher in the LLF OPO. Rates were between 59% and 134% higher for lung transplants in the LLF OPO. For heart, kidney-pancreas, pancreas, and intestine transplantation procedures, the range in the rate of transplant volumes was wide. The difference in annual heart transplant rates for the LLF OPO as compared to the WRTC OPO ranged from -26% to 32% for the period 2009-2013. The difference in annual kidney-pancreas transplants rates for the two OPOs was even wider, ranging from -50% to 123%, for the period 2009-2013. There were fewer than 20 pancreas transplants in both OPOs combined each year and ten or fewer intestine transplants each year, which lend themselves less to year-to-year and OPO-to-OPO trend comparisons than organ types with higher volumes.

**Table 2: Organ Transplant Volumes and Use Rates for OPO Residents, per Million Population, CY 2009-2013**

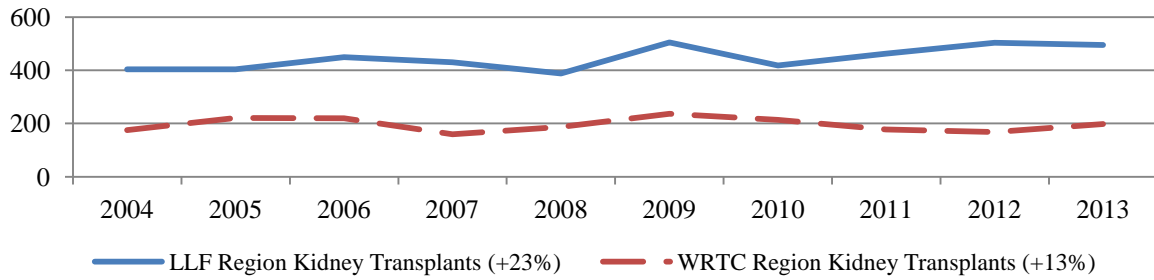
	<b>Organ Transplant Volumes</b>					<b>Use Rates</b>				
	2009	2010	2011	2012	2013	2009	2010	2011	2012	2013
<b>Kidney</b>	<b>696</b>	<b>615</b>	<b>641</b>	<b>660</b>	<b>670</b>	<b>81.10</b>	<b>70.80</b>	<b>73.02</b>	<b>74.37</b>	<b>74.72</b>
WRTC Region	333	318	339	336	362	69.17	64.97	68.30	66.71	70.89
LLF Region	363	297	302	324	308	96.35	78.33	79.17	84.42	79.78
Percent difference, LLF use rate compared to WRTC use rate						39%	21%	16%	27%	13%
<b>Liver</b>	<b>198</b>	<b>178</b>	<b>225</b>	<b>239</b>	<b>247</b>	<b>23.07</b>	<b>20.49</b>	<b>25.63</b>	<b>26.93</b>	<b>27.54</b>
WRTC Region	106	91	120	130	111	22.02	18.59	24.18	25.81	21.74
LLF Region	92	87	105	109	136	24.42	22.94	27.52	28.40	35.23
Percent difference, LLF use rate compared to WRTC use rate						11%	23%	14%	10%	62%
<b>Heart*</b>	<b>67</b>	<b>57</b>	<b>55</b>	<b>55</b>	<b>68</b>	<b>7.81</b>	<b>6.56</b>	<b>6.27</b>	<b>6.20</b>	<b>7.58</b>
WRTC Region	33	29	35	32	37	6.85	5.92	7.05	6.35	7.25
LLF Region	34	28	20	23	31	9.02	7.38	5.24	5.99	8.03
Percent difference, LLF use rate compared to WRTC use rate						32%	25%	-26%	-6%	11%
<b>Lung</b>	<b>58</b>	<b>59</b>	<b>46</b>	<b>62</b>	<b>42</b>	<b>6.76</b>	<b>6.79</b>	<b>5.24</b>	<b>6.99</b>	<b>4.68</b>
WRTC Region	25	21	19	28	18	5.19	4.29	3.83	5.56	3.52
LLF Region	33	38	27	34	24	8.76	10.02	7.08	8.86	6.22
Percent difference, LLF use rate compared to WRTC use rate						69%	134%	85%	59%	76%
<b>Kidney-Pancreas</b>	<b>32</b>	<b>30</b>	<b>29</b>	<b>21</b>	<b>18</b>	<b>3.73</b>	<b>3.45</b>	<b>3.30</b>	<b>2.37</b>	<b>2.01</b>
WRTC Region	23	11	17	10	9	4.78	2.25	3.42	1.99	1.76
LLF Region	9	19	12	11	9	2.39	5.01	3.15	2.87	2.33
Percent difference, LLF use rate compared to WRTC use rate						-50%	123%	-8%	44%	32%
<b>Pancreas</b>	<b>14</b>	<b>8</b>	<b>14</b>	<b>3</b>	<b>13</b>	<b>1.63</b>	<b>0.92</b>	<b>1.59</b>	<b>0.34</b>	<b>1.45</b>
WRTC Region	7	5	2	2	6	1.45	1.02	0.40	0.40	1.17
LLF Region	7	3	12	1	7	1.86	0.79	3.15	0.26	1.81
Percent difference, LLF use rate compared to WRTC use rate						28%	-23%	681%	-34%	54%
<b>Intestine</b>	<b>8</b>	<b>7</b>	<b>10</b>	<b>8</b>	<b>9</b>	<b>0.93</b>	<b>0.81</b>	<b>1.14</b>	<b>0.90</b>	<b>1.00</b>
WRTC Region	6	5	8	4	3	1.25	1.02	1.61	0.79	0.59
LLF Region	2	2	2	4	6	0.53	0.53	0.52	1.04	1.55
Percent difference, LLF use rate compared to WRTC use rate						-57%	-48%	-67%	31%	165%

\* Heart-lung transplants are not listed due to infrequency (1 in the MD Region in 2010 and 1 for the DC region in 2011).  
Sources: MHCC analysis of population and OPTN data as of April 25, 2014; Population data from the U.S. Bureau of the Census, University of Virginia Weldon Cooper Center, and Maryland Department of Planning

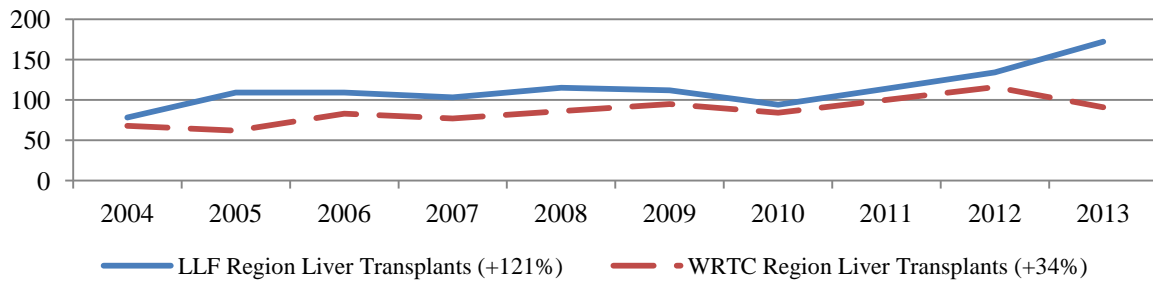
The figures below illustrate ten-year trends in selected transplant case volumes at transplant centers in the two OPO regions. Since 2004, the number of kidney and liver transplants in these OPOs has grown, while pancreas and kidney-pancreas transplants have either declined or remained steady. The volume of pancreas and kidney-pancreas transplants has declined nationally over the past ten years with advancements in insulin therapy. Additionally, according to staff at the Johns Hopkins Hospital, a key study published in 2003 in the *Journal of the American Medical Association* (JAMA) which concluded that solitary pancreas transplants may not positively impact survival rates for those with diabetes compared to conventional therapy led to programs to perform fewer pancreas transplants.<sup>21</sup>

<sup>21</sup> Venstrom, JM, et al. "Survival after pancreas transplantation in patients with diabetes and preserved kidney function. JAMA. 2003 Dec 3;290(21):2817-23. (website: <http://www.ncbi.nlm.nih.gov/pubmed/14657065>)

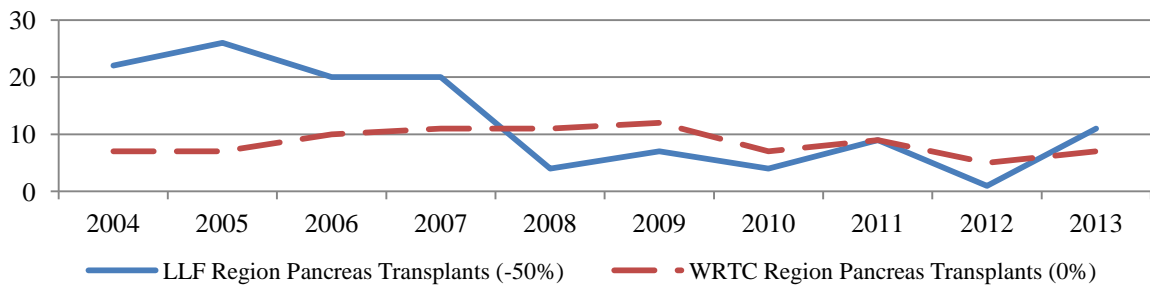
**Figure 2: Total Number of Kidney Transplants in OPO, CY 2004 - 2013**



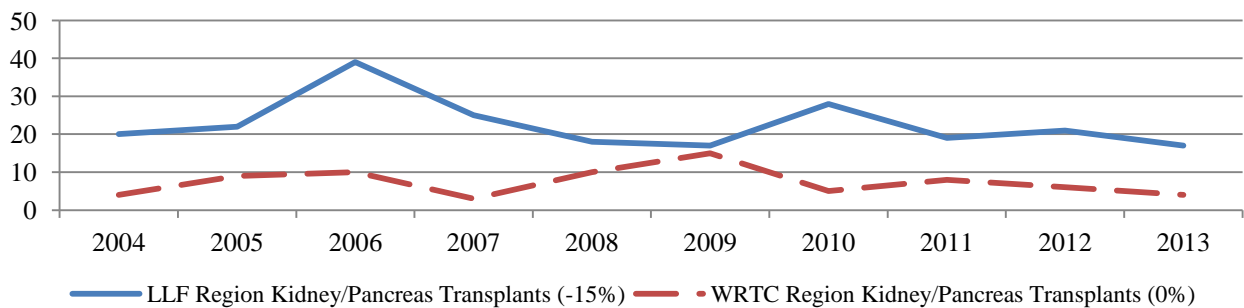
**Figure 3: Total Number of Liver Transplants in OPO, CY 2004-2013**



**Figure 4: Total Number of Pancreas Transplants in OPO, CY 2004-2013**



**Figure 5: Total Number of Kidney/Pancreas Transplants in OPO, CY 2004-2013**



Source: OPTN data as of April 25, 2014.

One of the goals of all OPOs is to maximize the number of organ donations in their jurisdiction. UNOS reports that LLF providers within the currently designated OPO region recovered 652 donor organs in the OPO in 2013, which equates to a donor rate of 168.9 per million population. WRTC providers recovered 532 organs for transplantation, a rate of 100.9 donor organs per million, as shown in Table 3 below.

**Table 3: Number of Donor Organs Recovered for Transplantation from OPO, CY 2013**

OPO	Kidney	Liver	Heart	Pancreas	Lung	Intestines	Kidney/ Pancreas	Total
<b>Total LLF</b>	449	127	18	22	35	1	-	<b>652</b>
<b>Total WRTC</b>	324	104	24	20	59	1	-	<b>532</b>

Source: OPTN data as of April 25, 2014

Regarding these trends, it is also important to consider concerns related to the importation of organs from outside of an OPO and matching recipients. For example, all costs associated with the organ donation process are billed to the recipient's OPO. Additionally, characteristics of donor and recipient pools may limit matches. Certain races and ethnicities are more likely to suffer from some end stage organ diseases for which organ transplantation is a treatment, such as kidney failure. While neither race, ethnicity, nor age, per se, come into play directly as factors in the matching process, organs from people with similar racial and ethnic backgrounds are often more compatible.<sup>22</sup> The following table displays the differences in the ethnicity of the pool of 2013 recipients and the current waiting list in OPOs serving Marylanders in regions currently designated by CMS. The challenge of matching minority organs may be exemplified through results in the LLF in 2013. In 2013, the majority of organ recipients were White/Caucasian (58%), while 35% of organs went to Black/African American recipients. This percentage breakdown is in contrast to the percentage of waiting list candidates by ethnicity in April 2014; more Black/African American candidates are on the waiting list than Whites/Caucasians (47% compared to 46%, respectively). The WRTC reports a higher percentage of its waiting list as Black/African American, which may play a factor in the number of transplants in the OPO, as well as the number of organs available from other OPOs that best match the patient population within the WRTC OPO.

<sup>22</sup> U.S. Department of Health and Human Services (website: <http://organdonor.gov/whydonate/minorities.html>)

**Table 4: Ethnicity of 2013 Transplant Recipients and 2014 Waiting List Candidates in LLF and WRTC**

Race/Ethnicity	LLF		WRTC	
	Transplant recipients, CY 2013	Waiting list candidates, as of 4/25/14	Transplant recipients, CY 2013	Waiting list candidates, as of 4/25/14
White	58%	46%	41%	28%
Black	35%	47%	43%	54%
Hispanic	2%	3%	6%	9%
Asian	4%	4%	9%	8%
American Indian/ Alaska Native	0%	0%	0%	0%
Pacific Islander	0%	0%	0%	0%
Multiracial	0%	0%	1%	0%

Source: MHCC analysis of OPTN data as of April 25, 2014.

When comparing the up-to-date waiting lists for patients in each OPO, Table 5 below shows that the wait lists are longer in the LLF than the WRTC for kidney, liver, kidney/pancreas, and lung transplants. The wait list for pancreas and heart transplants are longer in the WRTC. If a patient's resources allow, a Maryland resident can be placed on the wait list in multiple OPOs. However, in 2013, only three percent of Maryland residents who received kidney transplants received them outside of Maryland or D.C.

**Table 5: Number of Organ Donor Candidates on OPTN Wait List by Organ as of April 25, 2014**

	All Organs	Kidney	Liver	Pancreas	Kidney/ Pancreas	Heart	Lung	Heart/ Lung	Intestine
The Johns Hopkins Hospital	1,320	907	361	7	17	36	11	-	-
University of Maryland	1,867	1,424	353	21	29	22	17	1	-
<b>Total LLF</b>	3,187	2,331	714	28	46	58	28	1	-
Inova Fairfax Hosp	676	598	-	15	5	52	17	-	-
Children's National	20	16	-	-	-	4	-	-	-
Walter Reed National Military	130	126	-	4	1	-	-	-	-
Georgetown University	635	420	200	17	19	-	-	-	41
Washington Hospital Center	606	555	-	-	-	52	-	-	-
<b>Total WRTC</b>	2,067	1,715	200	36	25	108	17	0	41

Sources: MHCC analysis of OPTN data as of April 25, 2014.

## **Issues for Discussion in Updating the State Health Plan for Facilities and Services**

### *Changes in National Organ Transplantation Regions and Standards*

The following changes have taken place in national certification and designation processes for organ transplantation programs and may be addressed in an update of COMAR 10.24.15:

- CMS recertifies OPO DSAs every two to four years. The current certified WRTC DSA is not reflected in the latest update of COMAR 10.24.15. MHCC should align organ transplantation regional definitions with the most recently designated DSAs.
- VCAs were added to HHS' definition of organ transplantation with new policies effective in July 2014. MHCC and its advisory group members should consider whether adding these procedures to the list of regulated services in COMAR 10.24.15 is appropriate, based on likely or forecasted volumes of this service in the future.
- UNOS' program certification thresholds are published in the *Federal Register* and were updated in 2007. Transplant program re-approval volume requirements for kidney, liver, heart, lung, and intestine transplants programs are now an average of ten per year. The last revision of the SHP reflects national standards at the time, which have decreased by two transplants per year since that time for all organ transplant programs. While even lower national requirements for new kidney transplant programs are intended to resolve issues of access in remote areas, this is unlikely to be an issue in the State of Maryland. Both existing Baltimore-based transplant centers in Maryland, The Johns Hopkins Hospital and University of Maryland Medical Center, are within a three hour one-way driving time to most points in the state, centralized between a span from Garrett County to Worcester County.

The following table compares national volume requirements by organ type for CMS and volume requirements in selected states that regulate organ transplantation under CON programs. As shown in Table 6, generally, Maryland's minimum annual volume requirements fall within the range found in other states. Many of these state requirements were established after CMS' lower threshold was published in the *Federal Register* on March 30, 2007, and many states maintain higher thresholds than CMS. Of the states that have minimum volume requirements for each organ type: All have higher thresholds for kidney and lung transplant centers, and all but one have higher thresholds for liver and heart transplant centers; while only one state (Virginia) lists a volume requirement for intestine/small bowel.

**Table 6: National and Selected State Minimum Volume Requirements for Transplant Programs**

<b>Transplant Program Organ Type</b>	<b>Minimum Annual Volume Requirements</b>	<b>Effective Date of Requirements</b>
Kidney	U.S. CMS: 10*  Maryland: 30      Florida: 15 Iowa: 25          New Jersey: 25 New York: 20      North Carolina: 25 Virginia: 30      Washington: 15	U.S. CMS: March 30, 2007 Maryland: April 15, 2002 Florida: July 6, 2009 Iowa: July 4, 1990 Michigan: Sept. 28, 2012 New Jersey: June 16, 2014 New York: Dec. 31, 2013 North Carolina: Jan. 4, 1994, with amendments Nov. 1, 1996 Rhode Island: Sept. 2012 Virginia: April 1, 2009 Washington: 2003
Liver	U.S. CMS: 10  Maryland: 12      Florida: 5 within 2yrs Michigan: 12      New Jersey: 15 New York: 20      North Carolina: 15 Virginia: 21      Rhode Island: 20	
Pancreas	U.S. CMS: No requirement  Maryland: 12      New Jersey: 15 North Carolina: 10 Virginia: 12	
Heart	U.S. CMS: 10  Maryland: 12      Florida: 12 Michigan: 12      New Jersey: 12 New York: 14      North Carolina: 15 Rhode Island: 9      Virginia: 17	
Lung, Heart/Lung	U.S. CMS: 10 for lung, no requirement for heart/lung  Maryland: 12      Michigan: 12 Virginia: 12      North Carolina: 15	
Stem Cell:	North Carolina: 20	
Autologous	Maryland: 10      Florida: 10 Michigan: 20	
Allogeneic	Maryland: 10      Florida: 10 Michigan: 10	
Intestine/Small Bowel	U.S. CMS: 10  Maryland: no requirement Virginia: 2	

\* Note: Volume requirements for new kidney programs are set at 3 transplants per year and 10 for re-approval.

Sources: U.S. *Federal Register*, *Code of Maryland Regulations*, *Florida Administrative Code and Register*, *Iowa Administrative Code*, *Kentucky State Health Plan*, Michigan Department of Community Health, *New Jersey Administrative Code and Register*, New York Department of Health, North Carolina Office of Administrative Hearings, Virginia Department of Health.



MHCC's current net need projection for kidney transplants in the Washington region is three fewer than the current minimum volume requirement and 23 fewer transplants than the current required program threshold volume for the addition of a new program. Each kidney transplant program in the Washington region that serves adults met the threshold requirement of 50 for the last three years. The one program that did not report a minimum of 50 transplants was Children's University Medical Center. As shown in the latest need projections in Appendix I, in 2013 both kidney transplant programs in the Maryland region performed more than 100 more kidney transplants than any of the transplant programs in the Washington region. As a region, the Johns Hopkins Hospital and University of Maryland Medical Center combined performed more than twice as many kidney transplants as the combined four adult transplant programs in the DC region. A new kidney transplant program has been approved for establishment in the WRTC at George Washington University Hospital. In its application, this hospital submitted that its program would assist in improving organ transplant rates by increasing the number of donors and filling the gap in services left by the closure of Howard University's program in 2010.<sup>23</sup> Initially, the application was rejected by staff at the District of Columbia's Department of Health. The staff report noted that Howard's program only performed an average of 5 kidney transplants in its last ten years of operation.<sup>24</sup> However, the decision was appealed, and the application subsequently approved.

#### *Need Projections for Organ Transplants*

Maryland is one of 21 states, including D.C., which regulates organ transplantation under a Certificate of Need program.<sup>25</sup> Many of these states include methodologies for need projections in state regulations. In Maryland, need projections currently rely heavily on *past utilization* of a service. New Jersey also relies on current utilization, in terms of the impact of a new program on existing services, to determine need. Florida and New York incorporate the *potential for organ transplantation services* into their methodologies, using lists or incidence rates of patients with end stage organ failure. While Florida requires an applicant to present the number of organs procured by Florida hospitals in the most recent year in its application, it also considers the number of patients who meet commonly-accepted criteria identifying organ transplant candidates, like those with end stage organ failure or on dialysis. New York does not have a methodology to project the need for kidney transplants, but uses an incidence rate of 10 per one million to project the need for liver transplant services and 13.2 per one million to project the need for bone marrow transplant services. These rates are reviewed annually. Other states, such as Virginia and Michigan, assign a *specific number of programs* that should be available within a

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<sup>23</sup> Washington D.C. Department of Health State Health Planning & Development Agency's Certificate of Need Review Findings in the Matter of District Hospital Partners, L.P. George Washington University Hospital Certificate of Need Registration No. 12-2-8

<sup>24</sup> Washington D.C. Department of Health State Health Planning & Development Agency's Certificate of Need Review Findings in the Matter of District Hospital Partners, L.P. George Washington University Hospital Certificate of Need Registration No. 12-2-8

<sup>25</sup> National Conference of State Legislators (website: <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx>)

planning region. Virginia allows no more than one program for each transplantable organ in each planning region, while Michigan limits the number of heart, lung, and liver transplant programs to no more than three per region. North Carolina has limited its services to the five academic medical center teaching hospitals that currently provide this service. Still in others, such as Kentucky and Illinois, applicants bear the burden to present evidence regarding the need for additional programs for review by CON staff. In Kentucky, applicants must document that existing programs meet volume and quality standards, its ability to meet volume and quality standards, and the impact of its proposal on patient care, costs, quality and outcomes. In Illinois, this burden of evidence includes an applicant's assessment of its proposed service area, current utilization of other providers, impact of other providers, documentation of the historical number of referrals to other facilities, and physician attestation of the accuracy of projections.

Compared to other need projection methodologies, Maryland's is relatively more dependent on the past utilization of a service to forecast similar future utilization. Further, if MHCC projects no additional need for the service, the SHP does not allow for a proposed project to be considered. When updating COMAR 10.24.15, MHCC should evaluate its current need projection methodology and alternatives. MHCC could consider incorporating the number of patients on wait lists, the number of patients with end stage organ diseases, or the historic number of living donors for kidneys and liver in projecting the need for additional organ transplant services. However, the supply of organs is limited, and regardless of the need for organs, the addition of a new transplant program based on this need will not necessarily result in more transplants.

### *Stem Cell Transplantation Regulation*

Based on previous planning activities conducted by MHCC, the advisory group might consider whether stem cell and bone marrow transplant programs should be regulated on the same level as solid organ transplant programs. In reviewing other states' CON regulations, MHCC staff found that at least half of the states which regulate organ transplantation under a CON review process explicitly include bone marrow transplantation services.

COMAR 10.24.15 stipulates that these transplant programs shall meet accreditation requirements of the Foundation for the Accreditation of Cellular Therapy (FACT). FACT lists accredited programs for cellular therapy at the Johns Hopkins Hospital, the University of Maryland Medical Center, and Walter Reed National Military Medical Center in Maryland, and Children's National Medical Center in Washington, D.C. The volume of bone marrow and stem cell transplant procedures at The Johns Hopkins Hospital, the University of Maryland Medical Center, and Children's National Medical Center for the last ten years are included in Table 7 below. For these hospitals, there is not a consistent trend in the annual volume of these services over the period 2004 to 2013. The Johns Hopkins Hospital has had volumes between 112 and 155; University of Maryland has seen a general increase year to year, except declines in 2005 and 2012; and Children's National has seen volumes between 27 and 55, except for 2008 when it

reported one procedure code correlating to one marrow or stem cell transplant procedure code. The volumes experienced at Maryland facilities are well above the minimum annual volume requirement of 10 cases required by the current SHP.

**Table 7: Number of Bone Marrow and Stem Cell Transplant Procedures at the University of Maryland Medical Center, Johns Hopkins Hospital, and Children’s National Medical Center, 2004-2013**

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Johns Hopkins	155	126	124	112	130	127	125	125	131	134
University of Maryland	83	79	92	112	119	122	122	139	111	136
Children’s National	27	51	51	39	1	42	50	55	46	NA

Source: MHCC Staff analysis of HSCRC inpatient discharge abstract and DC inpatient discharge abstract. Volumes for Children’s National only available through 2012. Volumes include the following procedure codes: 4100, 4101, 4102, 4103, 4104, 4105, 4106, 4107, 4108, and 4109.

### *Disparities Between Maryland’s OPOs*

As described in this paper, organ procurement and transplantation specialty services are regulated and managed on multiple levels, federal and state government, quasi-governmental, and private. Several offices within the HHS, Maryland state government, UNOS, local OPOs (which operate within a regional organizational infrastructure), and transplant and donor recovery health care facilities regulate or manage transplant services. Different goals, priorities, and management processes at each level can affect the ultimate outcomes for potential transplant recipients. For example, while an OPO’s mission includes increasing the number of donor organs available, hospitals must weigh their CMS outcome requirements when accepting less-than-perfect organs for transplantation. Incongruent systems for performance measurement of this kind frame some of the ethical debates occurring in the field of organ transplantation.

Data presented here, along with other information, acknowledge geographic and racial disparities in organ transplantation services. Several studies and initiatives address solutions. The Scientific Registry of Transplant Recipients (SRTR) has investigated liver transplantation and the variance in OPO death rates and transplant rates, among other performance metrics. It found that some OPOs have a liver transplant rate that is twice the national average, while others have a liver transplant rate that is half of the average. This analysis suggests that more regionalized sharing of livers would decrease waitlist deaths, but may worsen geographic disparities. However, redistricting regional boundaries could minimize geographic disparity for this transplant service.<sup>26</sup>

To address the racial disparity in kidney transplants, UNOS changed the relative priority placed on a protein called HLA (Human Leukocyte Antigens) in 2003. HLA matches are found most often within the same race. However, advancements in immunosuppressants decrease the importance of HLA matching and can increase the chance of matching a White donor to an

<sup>26</sup> Scientific Registry of Transplant Recipients, “Addressing Geographic Disparities in Organ Availability.” (website: [http://www.srtr.org/publications/pdf/pres/2013/Addressing\\_Geographic\\_Disparities\\_in\\_Organ\\_Availability.pdf](http://www.srtr.org/publications/pdf/pres/2013/Addressing_Geographic_Disparities_in_Organ_Availability.pdf))

African American recipient. Research conducted by Johns Hopkins Medicine shows that the UNOS policy change has had the intended effect on decreasing kidney transplant disparities, but still acknowledges that African Americans are disadvantaged throughout the process due to higher prevalence of kidney failure and lower rates of referrals for transplant evaluations, placement on the waiting list, and obtaining a transplant once on the list.<sup>27</sup>

UNOS further amended its donor kidney allocation policies in 2013, which will take effect in 2014. The new criteria help to determine an estimated post-transplant survival rate to maximize the survival of recipients. By maximizing the time that recipients retain kidney function after a transplant, the change may also reduce the recipients' future need for repeat transplants and free up more transplants for first-time recipients. Additionally, kidneys with the shortest potential length of function will be offered on a wider geographic basis, which could decrease wait times across the country. Another policy change that will benefit historically disadvantaged patient populations is a change in calculating time on the wait list. Under the amended policy, wait time will be calculated based on the date a patient began dialysis or renal replacement therapy, instead of the date the patient is first listed with a transplant program.<sup>28</sup>

In Maryland, among other observations, recent data suggests that the LLF recovered more kidneys (125 more), livers (23 more), and more pancreas (2 more) in 2013 than the WRTC, while the WRTC recovered 6 more hearts and 24 more lungs for transplant than the LLF. Disparities in the number of patients on wait lists are also seen, with longer lists in the LLF for kidney, liver, kidney/pancreas, and lung transplants and longer wait lists in the WRTC for pancreas and heart transplants. Considering that the population in the LLF's DSA is approximately 73 percent that of the WRTC's total regional population, but the LLF recovered more total organs in 2013 and has longer waiting lists generally, the level of aggressiveness to both recover organs and place patients on wait lists varies among OPOs serving Marylanders.

However, comparing metrics across OPOs or across transplant programs does not always present an easy apples-to-apples comparison. There are differences in the management of OPOs and each transplant center or program, just as there are differences in the management of any health care service at acute care general hospitals. While disparities in organ transplantation practices may exist, it will be important to consider the scope of MHCC's regulatory authority for these specialized services.

MHCC includes standards to gauge quality outcomes of a service or facility in some SHP chapters to ensure that all patients at Maryland facilities receive a minimum level of quality. Under COMAR 10.24.15, Maryland's organ transplant programs must maintain certification

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<sup>27</sup> Johns Hopkins Medicine (website: [http://www.hopkinsmedicine.org/news/media/releases/national\\_policy\\_change\\_reduces\\_racial\\_disparity\\_in\\_kidney\\_transplants](http://www.hopkinsmedicine.org/news/media/releases/national_policy_change_reduces_racial_disparity_in_kidney_transplants))

<sup>28</sup> U.S. Department of Health and Human Services Health Resources and Services Administration (website: <http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=1600>)

from CMS and UNOS, which include experience and outcome requirements. Stem cell transplant programs must meet FACT requirements to maintain those services in Maryland.

### *Impact of Health Insurance Reform on Organ Procurement and Transplantation*

The 2010 Affordable Care Act (ACA) expanded access to health insurance for Americans. While Medicare has covered the cost of the organ transplants for transplant patients since 1968, the ACA allows young adults to remain on their parents' health insurance until the age of 26 and guarantees coverage for pre-existing conditions. This general increase in the pool of patients covered may further intensify the current unmet demand for transplants.

According to the American Medical Association, an important debate throughout the years for transplant patients relates to post-transplant coverage for immunosuppressant drugs. In 1978, Medicare extended benefits for post-transplant coverage. However, this did not include outpatient immunosuppressant drugs. In 1987, Medicare coverage was extended to 80 percent of the drug costs for one year after transplant. Medicare again extended coverage in 1997 to three years after transplant. In 2000, Medicare extended immunosuppressant coverage for the life of patients over 65 or with disabilities; however, younger Medicare patients continue to have no coverage after the initial three years. Gaps in post-transplant benefits were not specifically addressed in the ACA. While insurance exchanges may include lifetime coverage for immunosuppressive drugs, it is not clear exactly what type of coverage will be offered and whether lifetime coverage will be offered in the lower-priced health benefit plan options, where it is most needed.<sup>29</sup>

According to a study at Johns Hopkins, kidney donors have also faced difficulties in getting comparable coverage when they change carriers or plans. Challenges include denial of health insurance, higher rates, and being labeled with a pre-existing condition. The ACA attempts to mitigate these difficulties by mandating that health insurers cannot refuse coverage to living kidney donors or charge them a higher rate.<sup>30</sup>

Ultimately, payers and providers face mounting pressure to supply the most cost effective services with higher success rates. Considering the proven cost-effectiveness of kidney transplants, ensuring a higher level of success for organ transplantations would be arguably mutually beneficial for patients, transplant programs, and payers.<sup>31</sup> As payers consider the ramifications of not covering drugs that would help to ensure the long-term success of transplant recipients, they may decide to extend drug coverage. However, it is also possible that health insurance reform measures and pressure to cut costs may drive payers to narrow the number of

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<sup>29</sup> American Medical Association Journal of Ethics (website: <http://virtualmentor.ama-assn.org/2012/03/pdf/pfor3-1203.pdf>)

<sup>30</sup> Fiore, Christina. "Kidney Donation Hikes Insurance Denials." July 17, 2014. MedPage Today (website: <http://www.medpagetoday.com/Nephrology/KidneyTransplantation/46810>)

<sup>31</sup> American Medical Association Journal of Ethics (website: <http://virtualmentor.ama-assn.org/2012/03/pdf/pfor3-1203.pdf>)

providers within their own networks to cut costs. If networks become smaller, transition of care issues may disproportionately impact organ transplant candidates with end stage organ failure who typically have longer relationships with their care providers than other types of patients. Limiting network providers may also limit access to services within a region. When updating COMAR 10.24.15, MHCC might consider how these effects could impact the utilization and access to organ transplant services in Maryland.